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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,258	05/29/2001	Ivan Gout	040750-5002	2842

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,258	GOUT ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE f this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-78* is/are pending in the application.

4a) Of the above claim(s) *74-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-58,65 and 67-73* is/are rejected.

7)☒ Claim(s) *59-64 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of the Application

Claims 56-78 are pending.

Applicant's cancellation of claims 1-55 and addition of claims 56-78 in Paper No. 10, filed on 3/18/2003 is acknowledged.

Applicants argue that they are not aware of any condition in the PCT rules that all the claims originally presented must have been in Groups I or XIII to be considered for unity of invention. Furthermore, Applicants argue that no aspect of the PCT rules allow the special technical feature to be first chosen by the Examiner and then applied to the claims. Therefore, Applicants request that the finding of lack of unity in regard to Groups I and XIII (now claims 74-78) be reversed.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the lack of unity previously applied. The Examiner has not contended that all the claims as originally presented must have been in Groups I or XIII to be considered for unity of invention. The claims as originally presented were restricted to 14 Groups, therefore it is unclear to the Examiner as to how one could expect all the claims to be in only two groups. As indicated previously in Paper No. 9, mailed on 12/18/2002, the lack of unity analysis would have been different in regard to the special technical feature linking the groups if only the claims corresponding to Groups I and XIII were originally presented. However, the Examiner had to make a different analysis in regard to the special technical feature in view of the fact that all the claims, which were drawn to several inventions, had to be considered and not just those of Groups I and XIII. Furthermore, while it is agreed that pending claims 56-73 (Group I) and pending claims

74-78 (Group XIII) share the same special technical feature, i.e. the polynucleotide encoding the polypeptide of SEQ ID NO: 2, it is noted that according to 37 CFR 1.475(b), Groups I and XIII would also lack unity of invention in view of the fact that Groups I and Group XIII are directed to a polynucleotide (product) and two methods of use of said polynucleotide, i.e. a method of making a protein using the polynucleotide and a method of determining whether a cell expresses aberrant cellular levels using the polynucleotide. Elected Group I comprises claims drawn to the polynucleotide of SEQ ID NO: 1 (product) and a method of making a protein using said polynucleotide (method of use of such product). While a combination which includes a product and a process of use is contemplated in 37 CFR 1.475(b)(2), there is no combination set forth in 37 CFR 1.475(b) which contemplates a product and more than one process of use. As such, the lack of unity previously applied is deemed proper and therefore is made FINAL.

This application contains claims 74-78 drawn to an invention nonelected with traverse in Paper No. 8, filed on 10/28/2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 56-58 and 68-73 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 56 (claims 68-73 dependent thereon) is indefinite in the recitation of "the complement thereof" because it is unclear which "complements" are encompassed by the claim. Fragments of any size which are complementary to the polynucleotide claimed can be considered as "complements". Applicants have not define the term "complement", as it relates to size, in the specification either. If applicants wish to claim the entire complement of a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1, it is suggested that the term "complement" be replaced with "complete complement". For examination purposes, the suggested language will be used. Correction is required.

4. Claim 56 (claims 68-73 dependent thereon) is indefinite in the recitation of "molecule having at least about 85%" because it renders the claim vague and confusing. The use of this language is contradictory because the term "about" can be interpreted as "less than" whereas the term "at least" is synonym of "no less than". It is suggested that if Applicant's intended meaning is "85% or more", the claim be amended to recite "at least 85%" or similar. Applicants are reminded that the use of the term "about" by itself would also render the claim indefinite because the term "about" can be interpreted as both more and less. For examination purposes, the suggested language will be used. Correction is required.

5. Claims 57-58 (claims 67-73 dependent thereon) are indefinite in the recitation of "retains the same activity as a protein comprising the amino acid sequence of SEQ ID

NO: 2" as it is unclear absent a statement indicating the specific activity being referred to. As known in the art, a polypeptide can have more than one biological activity. Furthermore, as known in the art, any polypeptide can be used to raise antibodies, therefore the polypeptide of SEQ ID NO: 2 can have the activity of eliciting antibodies in addition to having S6 kinase activity. It is suggested that if the intended activity is that of an S6 kinase, the claim be amended accordingly. For examination purposes, it will be assumed that the activity being referred to is that of an S6 kinase. Correction is required.

6. Claim 57 (claims 67-73 dependent thereon) is indefinite in the recitation of "nucleic acid molecule which encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, wherein the protein contains one or more conservative amino acid substitutions" as it is unclear how a protein which comprises the amino acid sequence of SEQ ID NO: 2 can also comprise the amino acid sequence of SEQ ID NO: 2 with conservative substitutions. For examination purposes, the claim will be interpreted as being drawn to a polynucleotide which encodes a protein, wherein said protein is obtained by conservative substitution of one or more amino acids in the polypeptide of SEQ ID NO: 2. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 56-57, 65, 67-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. This rejection as it applies to cancelled claims 2-4, 16, 32-36, 38-40, has been discussed at length in Paper No. 9, mailed on 12/18/2002 and it is applied to newly added claims 56-57, 65 and 67-73 for the reasons of record.

10. Applicants argue that the new claims, which are directed to a variant or a fragment of SEQ ID NO: 2, provide the feature that they claimed nucleic acid encode a protein of the same activity as that of SEQ ID NO: 2, e.g. phosphorylation. Applicants direct the Examiner's attention to Example 8 in the specification.

11. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection as it applies to newly added claims 56-57, 65 and 67-73. Claims 56, 65 and 68 are directed to a genus of polynucleotides of any function wherein the polynucleotides have at least 85% sequence identity to that of SEQ ID NO: 1. Claims 57 and 67 are directed to a genus of polynucleotides encoding an S6 kinase wherein the S6 kinase is obtained by any number of conservative amino acid substitutions in the polypeptide of SEQ ID NO: 2. Claims 69-73 are drawn to vectors, host cells and method of producing a protein using the genera of polynucleotides of claims 56 and 57. While the Examiner acknowledges the information provided in Example 8, the specification does not disclose the functions of other polynucleotides which are 85% sequence homologs of the polynucleotide of SEQ ID NO: 1 nor does it disclose all the

amino acids which can be conservatively substituted in the polypeptide of SEQ ID NO: 2 and still retain activity. Furthermore, there is no disclosure of the critical structural elements which are required in a polynucleotide to encode an S6 kinase. The specification in Example 8 only discloses 2 variants of the polypeptide of SEQ ID NO: 2 which are active as S6 kinases: T401D and T412D (page 45, second paragraph), wherein only putative phosphorylation sites were substituted.

As indicated in previous Office Action Paper No. 9, the state of the art teaches that structural homologs may not be functional homologs and that small structural changes may lead to major changes in function. See the teachings of Bork, Van de Loo et al., Seffernick et al. and Broun et al. already discussed. Furthermore, Witkowski et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Therefore, the instant claims may potentially encompass polynucleotides of many unknown functions. In addition, the claimed genus of polynucleotides encoding S6 kinases is not adequately described since the specification does not disclose which amino acids can be conservatively substituted in the polypeptide of SEQ ID NO: 2 with the exception of two putative phosphorylation sites and there is no disclosure of the critical structural elements which cannot be conservative substituted. Thus, in view of the information provided by the disclosure, one skilled in the art cannot reasonably conclude that the claimed invention is adequately described.

12. Claims 56-57, 65, and 67-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) the polynucleotide of SEQ ID

NO: 1 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, (2) a polynucleotide encoding a polypeptide which result from substituting a threonine residue with an aspartic acid residue at position 401 of SEQ ID NO: 2, (3) host cells and vectors comprising (1) or (2), and (4) a method to produce the protein encoded by the polynucleotides of (1) or (2), does not reasonably provide enablement for (1) a polynucleotide of any function having at least 85% sequence identity to the polynucleotide of SEQ ID NO: 1 or (2) a polynucleotide encoding a protein which results from conservatively substituting any number of amino acids in the polypeptide of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

13. This rejection as it applies to cancelled claims 1-4, 16, 32-36, 38-40, has been discussed at length in Paper No. 9, mailed on 12/18/2002 and it is applied to newly added claims 56-57, 65 and 67-73 for the reasons of record.

14. Applicants argue that the new claims, which are directed to a variant or a fragment of SEQ ID NO: 2, provide the feature that they claimed nucleic acid encode a protein of the same activity as that of SEQ ID NO: 2, e.g. phosphorylation. Applicants direct the Examiner's attention to Example 8 in the specification.

15. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection in regard to newly added claims 56-57, 65 and 67-73. The scope of the claims, as described above, is not commensurate with the enablement provided since (1) there is no disclosure of other functions for the claimed polynucleotides, (2) there is no disclosure of the which amino acids can be conservatively substituted in the

polypeptide of SEQ ID NO: 2 and (3) there is no information as to which are the critical structural elements which cannot be conservatively substituted. As indicated previously, the state of the art teaches that structural homologs may not be functional homologs and that small structural changes may result in substantial changes in function. See the teachings of Bork, Van de Loo et al., Seffernick et al., Witkowski et al. and Broun et al. already discussed. Therefore, since other functions have not been disclosed, one would have to go through the burden of undue experimentation to determine the function of the claimed polynucleotides as well as how to use such polynucleotides. Furthermore, while the specification discloses two active S6 kinases wherein such kinases resulted from substitutions at a putative phosphorylation site in the polypeptide of SEQ ID NO: 2, the specification is silent in regard to (1) other amino acids in the polypeptide of SEQ ID NO: 2 which can be conservatively substituted and still retain activity and (2) which critical structures cannot be conservatively substituted. Therefore, one of skill in the art would have to go through the burden of undue experimentation to isolate those polynucleotides as encompassed by the claims which have S6 kinase activity. Thus, Applicants have not provided sufficient guidance to enable one of skill in the art to practice the full scope of the claimed invention.

Allowable Subject Matter

16. Claims 59-64 and 66 appear to be allowable over the prior art of record but are objected to since they depend upon rejected claim 56.

Conclusion

17. No claim is in condition for allowance.

18. Applicant's amendment, which cancelled claims 1-55 and added claims 56-73, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

20. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or

Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 15, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1600~~ 1600